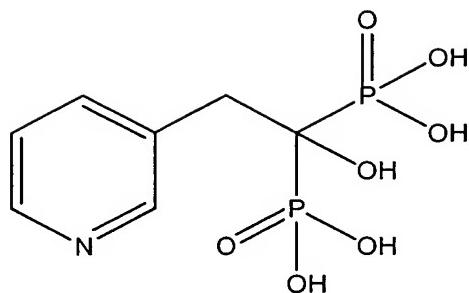


C L A I M S

1. The monosodium salt of 3-pyridyl-1-hydroxyethylidene-1,1-bisphosphonic acid in an amorphous form, having the X-ray diffraction pattern showing characteristic broad obtuse peak at 2θ angles ranging from 15 to 25 °, and, optionally, two sharp peaks at 2θ angles of 5.856 and 6.99 °.
2. The substance according to claim 1, characterized by characteristic broad obtuse peak at 2θ angles ranging from 17.4 to 20.2 °.
3. The substance according to claim 1, characterized by bands at 3084, 2936, 1633, 1051 and 120 cm⁻¹ in the Raman spectrum and by expanded bands at 139, 125, 75 and 37 ppm in the ¹³C CP MAS NMR spectrum.
4. The substance according to claim 1, characterized by two sharp peaks at 2θ angles of 5.856 and 6.99 ° and a broad band at 2θ 17.6 ° and a plateau without peaks between 2θ angles of 23 – 35 °.
5. The substance according to claim 4, characterized by expanded bands at 3085, 2786, 2379, 1561, 1212 and 809 cm⁻¹ in the IR spectrum and by expanded bands at 137.9, 124.5, 73.6, 36.8 ppm in the ¹³C CP MAS NMR spectrum.
6. The substance according to claim 3 or 4, having the water content of 0 to 7 % by weight.
7. The substance according to claim 6, having the water content of 4 to 7 % by weight.
8. The substance according to claim 3, having the water content of 7 to 10 % by weight.
9. The substance according to claim 8, having the water content of 9 to 10 % by weight.
10. A method of preparation of the substance according claim 3, characterized in that 3-pyridyl-1-hydroxyethylidene-1,1-bisphosphonic acid of formula I

5



10

I

in the crystalline form is heated at 60 to 200 °C for 1 to 48 hours.

11. The method according to claim 10, characterized in that the crystalline substance of formula I is used in the form of pentahydrate.

15 12. The method according to claim 10 or 11, characterized in that the crystalline substance of formula I is heated at 120 to 140 °C.

13. The method according to claim 11, characterized in that the pentahydrate of the substance of formula I is heated at 130 °C for 4 to 8 hours.

14. A method of preparation of the substance according claim 4, characterized in that 3-pyridyl-1-hydroxyethylidene-1,1-bisphosphonic acid in the crystalline form is heated at 20 50 to 120 °C, under a pressure of 10 to 100 kPa, for 1 to 48 hours.

15. The method according to claim 14, characterized in that the crystalline substance of formula I is used in the form of pentahydrate.

25 16. The method according to claim 14 or 15, characterized in that the crystalline substance of formula I is heated at 50 to 100 °C, the temperature being gradually elevated.

17. The method according to claim 15, characterized in that the pentahydrate of the substance of formula I is heated at 110 °C for 18 to 48 hours.

18. The method according to claim 15 or 16, characterized in that heating is carried out under a reduced pressure, preferably at 10 to 30 kPa.

30 19. A method of preparation of the substance according claim 8, characterized in that a solution of risedronate sodium is spray dried in a stream of a gas.

20. The method according to claim 19, characterized in that the spray drying is applied to a solution of risedronate sodium having the concentration of 1 to 250 g/l in water, optionally in a mixture of water with a C1 to C4 alcohol.
- 5 21. The method according to claim 19 or 20, characterized in that the solution of risedronate is heated to 20 to 100 °C before being fed to the drier.
22. The method according to any of claims 19, 20 and 21, characterized in that the drying is carried at a temperature of the feed nozzle region of the drier ranging from 70 to 220 °C.
- 10 23. The method according to any of claims 19-22, characterized in that the gas outlet from the spray dryer has a temperature of 40 to 150 °C.
24. The method according to claim 22 or 23, characterized in that the temperature of the outlet gases from the drier is maintained at 50 to 70 °C.
- 15 25. A pharmaceutical formulation, characterized in that it contains the substance in the amorphous form according to claim 1 and at least one other pharmaceutically utilizable substance.
26. The pharmaceutical formulation according to claim 25, characterized in that it is a tablet containing a combination of mannitol and microcrystalline cellulose.
27. The pharmaceutical formulation according to claim 25 or 26, characterized in that it contains 5 or 35 mg of the active substance.

20